This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances, and the establishment of international biological reference materials.

Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development of revised WHO Guidelines. Specific discussions took place on the development of WHO guidance on the nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines; the quality, safety and efficacy of typhoid conjugate vaccines; and the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology.

Subsequent sections of the report provide information on the current status and proposed development of international reference materials in the areas of vaccines and related substances; blood products and related substances; in vitro diagnostic device reagents; and biotherapeutics other than blood products.

A series of annexes are then presented which include an updated list of WHO Recommendations, Guidelines and other documents on biological substances used in medicine (Annex 1), followed by a series of WHO Guidelines adopted on the advice of the Committee (Annexes 2–4). All additions and discontinuations made during the 2013 meeting to the list of International Standards and Reference Panels for biological substances maintained by WHO are summarized in Annex 5. The updated full catalogue of WHO International Reference Preparations is available at: http://www.who.int/bloodproducts/catalogue/en/.

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21 to 25 October 2013

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